

Appln No. 10/670,950
Amdt date September 14, 2006
Reply to Office action of June 14, 2006

REMARKS/ARGUMENTS

Claims 18-42 and 51-58 are pending in the above-referenced application.

Claims 1-17 and 43-50 have been canceled without prejudice. Claims 18, 25-32 and 42 have been amended as indicated above and claims 51-58 added to further define Applicant's invention. Support for claims 51-58 can be found throughout the specification. No new matter has been added.

This is a Response to the Office Action dated June 14, 2006 wherein the Examiner rejected claims 18, 21, 23, and 27 under §102(b) as being anticipated by Pat. No. 5,829,976 to Green; rejected claims 18, 21, 23, and 26 under §102(b) as being anticipated by Pat. No. 1,362,937 to Grace; rejected claims 19, 20, 22, 24, 31, 32, 34-37 and 42 under §103(a) as being obvious over Green in view of Pub. No. 2003/0232310 to Matthews et al.; rejected claims 19, 20, 22, 24, 31, 32, 34-37 and 42 under §103(a) as being obvious over Grace in view of Mathews et al.; rejected claims 25 and 28 under §103(a) over Grace and Green, respectively; and rejected claims 33 and 38-41 under §103(a) as being unpatentable over Green or Grace in view of Matthews et al. and further in view of Pat. No. 6,083,489 to Fischer et al.

In view of the amendments indicated above and the remarks that follow, reconsideration and an notice of allowance are respectfully requested.

§102(b) Rejection of Claims 18, 21, 23, and 27 by Green

In rejecting claims 18, 21, 23, and 27, the Examiner contends that Green discloses a therapeutic dental delivery device essentially as claimed including an applicator that

Appln No. 10/670,950

Amdt date September 14, 2006

Reply to Office action of June 14, 2006

"is a felt tip 18" and an activator that "is a push button." Because claims 21 and 23 have been canceled, their rejections are moot.

To anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Therefore, all claim elements, and their limitations, must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102.

Independent claim 18 as amended, recites a therapeutic dental delivery device for treating a condition in an oral cavity of a subject, comprising: a liquid oral therapeutic dental composition; an applicator for applying the composition to the oral cavity selected from the group consisting of a brush and a roller ball; an activator selected from the group consisting of a click mechanism and a push button; a cap for covering the applicator; the cap having an open end terminating at a position between the activator and the applicator; and a reservoir located between the applicator and the activator and configured to store the composition, wherein the activator is configured to dispense the composition from the reservoir to the applicator.

Applicant respectfully submits that Green does not anticipate claim 18 by disclosing each and every element of the recited dental delivery device. Among other things, Green discloses a device that comprises a disposable tip 20 having a nonwoven tufted scrub material 18 attached to a flexible probe 24. [See Col. 2, lines 56-60]. "[T]he scrub material 18 is rugged enough to scrub away plaque on the too surface of a tooth,

Appln No. 10/670,950

Amdt date September 14, 2006

Reply to Office action of June 14, 2006

dense enough to protect the cannula core, and soft enough to be non-irritating to gingival tissue, yet porous to allow medicament to flow through it." [See Col. 2, lines 65 to Col. 3 line 2]. "The size and flexible nature of the flexible probe 24 permits insertion of the fibers into tight recesses between teeth or between the gum line and the tooth." [See Col. 3, lines 28-31]. Thus, the probe 24, as the name suggests, is intended for probing and scrubbing, not for delivery in the manner recited.

More importantly, Green contrasted and taught away from using brush bristles as bristles cannot be used to scrub the teeth. ["In contrast to brush bristles, several features of the scrub material 18 make it suitable for use in the invention." [See Col. 2, lines 63-64].

Accordingly, because Green does not disclose a dental delivery device in which an applicator for applying the composition to the oral cavity is selected from the group consisting of a brush and a roller ball, Green cannot anticipate claim 18 as required under §102(b).

Dependent claim 27 depends from claim 19, which depends from claim 18 is also rejected under §102(b) as being anticipated by Pat. No. 5,829,976 to Green. While Applicants do not acquiesce with the particular rejections to dependent claim 27, it is believed that these rejections are moot in view of the remarks made in connection with independent claim 18. Dependent claim 27 include all of the limitations of the base claim and any intervening claim, and recite additional features which further distinguish it from the cited reference. Therefore, dependent claim 27 is also allowable for at least the same reason as claim 18.

Appln No. 10/670,950

Amdt date September 14, 2006

Reply to Office action of June 14, 2006

Applicant respectfully requests that the rejection of claims 18 and 27 under §102(b) as being anticipated by Pat. No. 5,829,976 to Green be withdrawn. Reconsideration is respectfully requested.

§102(b) Rejection of Claims 18, 21, 23, and 26 by Grace

In rejecting claims 18, 21, 23, and 26, the Examiner contends that Grace discloses a therapeutic dental delivery device essentially as claimed including a brush applicator and a twist mechanism activator. Because claims 21 and 23 have been canceled, their rejections are moot.

Claim 18 as amended recites a therapeutic dental delivery device for treating a condition in an oral cavity of a subject, comprising: a liquid oral therapeutic dental composition; an applicator for applying the composition to the oral cavity selected from the group consisting of a brush and a roller ball; an activator selected from the group consisting of a click mechanism and a push button; a cap for covering the applicator; the cap having an open end terminating at a position between the activator and the applicator; and a reservoir located between the applicator and the activator and configured to store the composition, wherein the activator is configured to dispense the composition from the reservoir to the applicator.

Grace disclose a brush including a brush head 30 having a plurality of bristles 31, a twist cap 40 for driving a plunger rod 34 to push a composition within a refillable cartridge 26 out through a duct 27 and a branch passage 29 to then be applied to a surface by the bristles 31.

Appln No. 10/670,950

Amdt date September 14, 2006

Reply to Office action of June 14, 2006

Grace does not disclose an activator selected from the group consisting of a click mechanism and a push button and a cap having an open end as claimed. Accordingly, Grace cannot anticipate claim 18.

Because claim 26 depends from claim 18, it is patentable over Grace for at least the same reasons as claim 18.

Applicant respectfully requests that the rejection of claims 18 and 26 under §102(b) as being anticipated by Pat. No. 1,362,937 to Grace be withdrawn. Reconsideration is respectfully requested.

§103(a) Rejection of Claims 19, 20, 22, 24, 31, 32, 34-37, and

42 by Green in view of Matthews et al.

In rejecting claims 19, 20, 22, 24, 31, 32, 34-37, and 42, the Examiner contends that Green discloses essentially as claimed except it does not disclose the claimed composition. However, the Examiner contends that Matthews et al. disclose "a device comprising a liquid oral therapeutic dental composition comprising a moisture sensitive polymer complex and a water soluble salt and hydrogen peroxide or carbamide peroxide" and that it would have been obvious to combine Green with Matthews et al. to render the rejected claims obvious. Because claims 22 and 24 have been canceled, their rejections are moot.

Three criteria must be met to establish a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior

Appln No. 10/670,950
Amdt date September 14, 2006
Reply to Office action of June 14, 2006

art reference, or combination of references, must teach or suggest all the claim limitations. MPEP § 2142.

Because Green does not disclose a dental delivery device for applying a composition using an applicator selected from the group consisting of a brush and a roller ball and because Matthews et al. is relied on to disclose a composition, the combination of Green in view of Matthews et al. failed to disclose all of the claim limitations of claim 18.

Claims 19, 20, 31, 32, and 34-37 are dependent claims and depend, either directly or indirectly, from claim 18. While Applicants do not acquiesce with the particular rejections to these dependent claims, it is believed that this rejection is moot in view of the remarks made in connection with independent claim 18. The dependent claims include all of the limitation of the base claim and any intervening claims, and recite additional features which further distinguish the claims from the cited references. Accordingly, because they depend from claim 18, claims 19, 20, 31, 32, and 34-37 are patentable over the combination of Green in view of Matthews et al.

Independent claim 42 has been amended to recite a dental therapeutic kit comprising: a liquid oral therapeutic dental composition comprising a moisture responsive gel carrier comprising a functional polymer and a therapeutic agent, the dental composition having a starting viscosity; a delivery device comprising: an applicator for applying the composition to the oral cavity; an activator; and a reservoir located between the applicator and the activator and configured to store the composition, wherein the activator is configured to dispense the composition from the reservoir to the applicator; and a set of instructions for applying the therapeutic dental

Appln No. 10/670,950

Amdt date September 14, 2006

Reply to Office action of June 14, 2006

composition; and wherein the dental composition has a used viscosity, which is higher than the starting viscosity.

Applicant submits that the combination of Green in view of Matthews et al. does not disclose all of the claimed limitations, nor motivates or teaches one to arrive at the invention of claim 42. Among other things, the dental therapeutic kit recited by claim 42 comprises a dental composition comprising a functional polymer and a therapeutic agent, the dental composition having a starting viscosity and wherein the dental composition has a used viscosity, which is higher than the starting viscosity. While Matthew et al. discloses a tackifying agent, no such combination as claimed can be found in the Matthew et al. reference. Accordingly, Applicant submits that the combination fails to render claim 42 obvious.

Furthermore, Applicant respectfully submits that since Matthews et al. disclose a brush-on type applicator, the need to have or a desire to provide a dental composition having different viscosities between a starting point and a used point is immaterial. Thus, it would not have been obvious to combine Matthews et al.

Reconsideration is respectfully requested.

§103(a) Rejection of Claims 19, 20, 22, 24, 29, 30, 34-37, and

42 by Grace in view of Matthews et al.

In rejecting claims 19, 20, 22, 24, 29, 30, 34-37, and 42, the Examiner contends that Grace discloses a device essentially as claimed but not the claimed composition. However, the Examiner contends that Matthews et al. disclose "a device comprising a liquid oral therapeutic dental composition comprising a moisture sensitive polymer complex and a water soluble salt and hydrogen peroxide or carbamide peroxide" and

Appln No. 10/670,950
Amdt date September 14, 2006
Reply to Office action of June 14, 2006

that it would have been obvious to combine Grace with Matthews et al. to render the rejected claims obvious. Because claims 22 and 24 have been canceled, their rejections are moot.

As discussed above, Grace discloses a brush having a plurality of bristles. However, Grace does not disclose an activator selected from the group consisting of a click mechanism and a push button and a cap having an open end as claimed. As the Matthews et al. reference is relied on to disclose a composition, the combination of Grace in view of Matthews et al. failed to render claim 18 obvious.

Claims 19, 20, 31, 32, and 34-37 depend, either directly or indirectly, from claim 18 and therefore are allowable over the combination for at least the same reasons as claim 18.

Regarding independent claim 42, Applicant submits that the combination of Grace in view of Matthews et al. does not disclose all of the claimed limitations. Among other things, the dental therapeutic kit recited by claim 42 comprises a dental composition comprising a functional polymer and a therapeutic agent, the dental composition having a starting viscosity and wherein the dental composition has a used viscosity, which is higher than the starting viscosity. While Matthews et al. discloses a tackifying agent, no such combination as claimed can be found in the Matthews et al. reference. Accordingly, Applicant submits that the combination failed to render claim 42 obvious.

Furthermore, Applicant submits that since Matthews et al. disclose a brush-on type applicator, the need to have or a desire to provide a dental composition having different viscosities between a starting point and a used point is immaterial. Thus, it would not have been obvious to combine Matthews et al. with Grace.

Appln No. 10/670,950
Amdt date September 14, 2006
Reply to Office action of June 14, 2006

Reconsideration is respectfully requested.

§103(a) Rejection of Claims 25 and 28 by Grace and Green, Respectively

In rejecting claims 25 and 28, the Examiner contends that the various activators claimed and not disclosed by Green or Grace are nonetheless not patentable as they involve routine skill in the art.

As claim 28 has been amended to eliminate any reference to an activator, its rejection is moot.

Regarding claim 25, it recites the device of claim 18, wherein the applicator is a brush and wherein the activator is a push button configured to dispense the composition to the brush applicator. Green, as discussed above, is inapposite as it is directed to a probing instrument. Furthermore, Green teaches away from a brush having a plurality of bristles.

Regarding the Grace reference, it fails to disclose a cap and an activator selected from the group consisting of a click mechanism and a push button. Applicant submits that the twist cap used in the Grace reference cannot be arbitrarily changed to other activators for the reasons discussed in the Background section of the specification. In particular, prior art compositions tend to be viscous for applying onto a dental tray or of low viscosity when used with other delivery medium, such as the Simply White and the Whitestrips dental systems. Thus, one cannot simply replace a twist cap design for other activators without also considering flow characteristics of the dental composition and how the composition is to be delivered to the dental arch. Said differently, there must be some teaching-suggestion-motivation in the prior art to match the delivery

Appln No. 10/670,950

Amdt date September 14, 2006

Reply to Office action of June 14, 2006

device with a particular activator in view of the dental composition, which is not shown by Grace.

Regarding claim 28, it has been amended as indicated above, which makes the rejection moot. Furthermore, as claim 28 depends from claim 18, it is allowable over Grace and Green for at least the same reasons as claim 18.

Reconsideration is respectfully requested.

§103(a) Rejection of Claims 33 and 38-41 by

Green or Grace in view of Mathews et al. and Fischer et al.

In rejecting claims 33 and 38-41, the examiner contends that "[t]he modified device of Green or Grace and Matthews et al. shows the limitations as described above; however, admits that they do not show [a] gel carrier polymer including polyvinylpyrrolidone." The Examiner then relied on Fischer et al. to show a carrier including carboxypolymethylene and polyvinylpyrrolidone and contends that it would have been obvious to one having ordinary skill in the art to modify the device to include the thickener taught by Fischer et al.

Regarding claim 33, it depends from claim 20, which depends from claim 18. Because Green failed to disclose the limitations of claim 18, as discussed above, the rejection in view of Green is traversed. Moreover, the combination further in view of Fischer et al. also failed to disclose the limitations recited by claim 33. Among other things, claim 33 recites "the device of claim 20, wherein the moisture sensitive polymer complex comprises carboxypolymethylene and polyvinylpyrrolidone."

The Examiner referred to col. 8, line 20 of the Fischer et al. reference to disclose the moisture sensitive polymer complex recited by claim 33. However, a review of the

Appln No. 10/670,950
Amdt date September 14, 2006
Reply to Office action of June 14, 2006

Fischer et al. reference shows that a list of exemplary thickeners are provided but there is no teaching whether and which combination of the plurality of examples may be used together. In other words, there is no teaching, suggestion or motivation that shows that from the list of thickeners, carboxypolymethylene and polyvinylpyrrolidone may be used together as a combination. Indeed, there is no disclosure in the Fischer et al. reference wherein a composition has a low viscosity for dispensing purposes (i.e., so that it may be used with a delivery device) and subsequently increase in viscosity in the presence of saliva or water to resist running or migrating when applied to the teeth. Accordingly, there is no motivation or suggestion that both carboxypolymethylene and polyvinylpyrrolidone may be used together as a combination.

The section of the '489 Fischer et al. reference that discusses thickening agents is reproduced below in its entirety:

3. Thickening Agents

A common constituent within a carrier will be a thickening material, which may be used to provide bulk and a suitable consistency. Thickeners may be especially important in the case where the dentifrice compositions are foamed since they may assist in stabilizing the entrained gas. They also may help keep the foamed composition firm and from having a liquid consistency.

Appropriate thickeners may include either inorganic organic thickeners, or both. Inorganic thickeners that may be included in the dentifrice and toothpaste compositions of the present invention include flumed silicas dispersed in water, such as Cab-o-sil available from Cabot

Appln No. 10/670,950
Amdt date September 14, 2006
Reply to Office action of June 14, 2006

Corporation, and thickening silicas, including those available from W. R. Grace designated as Sylox 15.

Appropriate organic thickeners include natural and synthetic gums and colloids. Examples of organic thickeners include carrageenan (derived from Irish moss), xanthan gum, guar gum, other polysaccharide gums, sodium carboxymethyl cellulose, starch, polyvinylpyrrolidone, hydroxyethylpropylcellulose, hydroxybutylmethylcellulose, hydroxypropylmethylcellulose, hydroxyethylcellulose, other cellulosic ethers, and carboxypolymethylene. Such materials are typically dispersed in water and/or other solvents, such as glycerine or polyethylene glycol.

Thickening materials will preferably be incorporated in the compositions of the present invention in a concentration in a range from about 0.05% to about 25% by weight of the composition, and preferably in a range from about 0.1% to about 10% by weight.

Furthermore, of the 12 different compositions disclosed between column 15 and column 24 of the '489 Fischer et al. reference, none of the compositions show a combination of carboxypolymethylene and polyvinylpyrrolidone used as a moisture sensitive polymer complex. Reconsideration is respectfully requested.

Regarding independent claim 38, it recites a therapeutic dental pen for treating a condition in an oral cavity of a subject, comprising: a liquid oral therapeutic dental composition comprising a moisture responsive gel carrier and a therapeutic agent dispersed in the responsive gel carrier, wherein the gel carrier comprises a polymer complex including carboxypolymethylene and polyvinylpyrrolidone and a water

Appln No. 10/670,950
Amdt date September 14, 2006
Reply to Office action of June 14, 2006

soluble salt; a brush-on applicator for applying the composition to the oral cavity; a push button; and a reservoir located between the applicator and the push button and configured to store the composition, wherein the push button is configured to dispense the composition from the reservoir to the applicator.

Thus, claim 38 clearly recites, in part, a therapeutic dental pen comprising a polymer complex gel carrier including carboxypolymethylene and polyvinylpyrrolidone and a water soluble salt. As discussed with reference to the allowance of claim 33 above, Applicant submits that the Fischer et al. reference does not make up for the deficiencies of Green or Grace and Matthews et al. Accordingly, Applicant submits that the combination failed to render claim 38 obvious.

Because claims 39-41 depend from claim 38, they too are allowable for at least the same reasons as claim 38.

Reconsideration is respectfully requested.

New claims 51-58

New claims 51-58 are dependent claims and claim from independent claim 42. Thus, claims 51-54 are allowable for at least the same reasons as claim 42.

Conclusion

In view of the amendments and remarks set forth above, Applicant respectfully submits that the application is in condition for allowance and early notice thereof is respectfully solicited.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact the undersigned at 31-845-8501.

Appln No. 10/670,950
Amdt date September 14, 2006
Reply to Office action of June 14, 2006

Dated: September 14, 2006

Respectfully submitted,



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